

## DRAFT Medical Coverage Policy | Digestive Enzyme Cartridges



**EFFECTIVE DATE:** 06|01|2023

**POLICY LAST UPDATED:** 02|16|2023

### OVERVIEW

This policy describes the reimbursement for digestive enzyme cartridges (e.g. Relizorb).

RELIZORB™ (Alcresta Pharmaceuticals) is a single use digestive enzyme cartridge indicated for use in individuals to break down enteral formula. It is designed to hydrolyze fat present in the enteral formula from triglycerides into fatty acids and monoglycerides to allow for their absorption by the body. This breakdown of fats is intended to mimic the function of the enzyme lipase in individuals who do not excrete sufficient levels of pancreatic lipase.

### MEDICAL CRITERIA

None

### PRIOR AUTHORIZATION

Preauthorization is not required.

### POLICY STATEMENT

#### Medicare Advantage Plans

Digestive enzymes added to enteral formula via a cartridge device attached to the tubing used for enteral feeding (eg, Relizorb™ immobilized lipase cartridge) is considered medically necessary for chronic medical conditions. These conditions include, but are not limited to, individuals with Cystic Fibrosis, Crohn's Disease or Ulcerative Colitis with complications, and Pancreatic disorders. Refer to Coding section for details.

#### Commercial Products

Effective November 1, 2019, digestive enzymes added to enteral formula via a cartridge device attached to the tubing used for enteral feeding is considered not covered for Medicare Advantage Plans products and not medical necessary for Commercial products (eg, Relizorb™ immobilized lipase cartridge) as the evidence is insufficient to determine the effects of the technology on health outcomes.

### COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, Subscriber agreement for the applicable "Medical Equipment, Medical Supplies and Prosthetic Devices" coverage.

### BACKGROUND

#### Commercial Products

Relizorb is considered a first of its kind enzyme cartridge. It is designed to mimic the action of pancreatic lipase for use in adults receiving enteral tube feedings. Relizorb is a digestive enzyme cartridge that is used in adults to help break down (digest) the fats in enteral tube feeding formula into an absorbable form the body can use. It was approved by the FDA for this indication. However, large scale studies in human subjects are still lacking. Therefore, there is an insufficient evidence to determine that the technology results in a meaningful improvement in the net health outcome.

### CODING

#### Medicare Advantage Plans

**The following code is covered when filed with a covered ICD-10 code below:**

**B4105** In-line cartridge containing digestive enzyme(s) for enteral feeding, each

## Covered DX for HCPCS Code B4105 for Medicare Advantage Plans

### Commercial Products

**The following code is not medically necessary for Commercial Products**

**B4105** In-line cartridge containing digestive enzyme(s) for enteral feeding, each

### RELATED POLICIES

Coding and Payment Guideline

Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations

### PUBLISHED

Provider Update, April 2023

Provider Update, April 2022

Provider Update, May 2021

Provider Update, September 2019

Provider Update, February 2019

### REFERENCES

1. Centers for Medicare and Medicaid Services, Local Coverage Determination (LCD), Noridian Healthcare Solutions, LLC, L38955, Enteral Nutrition.
2. Centers for Medicare and Medicaid Services, Local Coverage Determination Article, Noridian Healthcare Solutions, LLC, A58833, Enteral Nutrition.
3. Alcresta Therapeutics at <http://relizorb.com/> Accessed May 16, 2018
4. [http://www.accessdata.fda.gov/cdrh\\_docs/pdf16/K163057.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf16/K163057.pdf) Section 510k premarket summary approval. Accessed May 16, 2018.
5. Freedman S, Orenstein D, Black P, et al. Increased fat absorption from enteral formula through an in-line digestive cartridge in patients with cystic fibrosis. *J Pediatr Gastroenterol Nutr.* 2017 Jul;65(1):97-101.

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